

JUN 14 2004

510(k) Safety Summary

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**A. Name of Device**

- Trade Name: Stellartech Coagulation System
- Common Name: Electrosurgical Unit and Accessories
- Classification Name: Device, Electrosurgical Cutting and Coagulation and Accessories (21 CFR 878.4400)

**B. Predicate Devices**

<u>Device</u>	<u>Premarket Notification</u>
Stellartech Coagulation System	K013139, 12/18/01
Stellartech Coagulation System	K023765, 11/29/02
Stellartech Coagulation System	K032062, 07/29/03
Stellartech Coagulation System	K032452, 08/21/03
Stellartech Coagulation System	K032721, 10/06/03
Stellartech Coagulation System	K040240, 04/01/04

**C. Device Description:**

The Stellartech Coagulation System consists of the following components.

- Stellartech Coagulation Catheter
- Stellartech Coagulation Catheter Connection Module
- Stellartech Coagulation Generator
- Stellartech Sheath
- Optional Stellartech Footswitch.
- Optional Stellartech Sizing Catheter
- Optional Stellartech Sizing Sheath

The proximal end of the Stellartech Coagulation Catheter connects to the Stellartech Coagulation Catheter Connection Module. The Stellartech Coagulation Catheter Connection Module cable connects to the Stellartech Coagulation Generator.

**D. Indicated Use**

The Stellartech Coagulation System is indicated for use in the coagulation of bleeding and non-bleeding sites in the gastrointestinal tract including but not limited to, the esophagus. Indications include Esophageal Ulcers, Mallory-Weiss tears, Arteriovenous Malformations, Angiomata, Barrett's Esophagus, Dieulafoy Lesions, and Angiodysplasia.

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**E. Technical characteristics**

The technological characteristics of the Stellartech Coagulation System are substantially equivalent to those of the above listed predicate devices.

**F. Summary**

By virtue of design, principles of operation, materials and intended use, the Stellartech Coagulation System is substantially equivalent to devices currently marketed in the United States.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN 14 2004

Mr. Gary Seeger  
Vice President, Regulatory Affairs/Quality Assurance  
Stellartech Research Corporation  
1346 Bordeaux Drive  
Sunnyvale, California 94089

Re: K041383  
Trade/Device Name: Stellartech Coagulation System  
Regulation Number: 21 CFR 878.4400  
Regulation Name: Electrosurgical cutting and coagulation device and accessories  
Regulatory Class: II  
Product Code: GEI  
Dated: May 24, 2004  
Received: May 25, 2004

Dear Mr. Seeger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

*Miriam C. Provost*  
for Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN):

K041383

DEVICE NAME: Stellartech Coagulation System

INDICATIONS FOR USE:

The Stellartech Coagulation System is indicated for use in the coagulation of bleeding and non-bleeding sites in the gastrointestinal tract including but not limited to, the esophagus. Indications include Esophageal Ulcers, Mallory-Weiss tears, Arteriovenous Malformations, Angiomata, Barrett's Esophagus, Dieulafoy Lesions, and Angiodysplasia.

Miriam C. Provost  
(Division Sign-Off)  
**Division of General, Restorative,  
and Neurological Devices**

**510(k) Number** K041383

Prescription Use X  
(Part 21 CFR 801.Subpart D)

AND/OR

Over-The-Counter-Use \_\_\_\_\_  
(21 CFR 807.Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)